

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions and listings of claims in the application:

1. (Currently amended) A method of ~~minimizing minimization~~ of the likelihood of false-positive and false-negative results in the detection of small amounts of amniotic fluid in ~~the a~~ vaginal secretion of a pregnant ~~woman women, and strip device based on the method~~, which method comprises:

(i) ~~Selecting of selecting~~ a highly specific pair of monoclonal antibodies for the determination of ~~the a~~ minimum background concentration of Placental Alpha-1-Microglobulin (PAMG-1) in a vaginal secretion ~~of a pregnant woman~~; and

(ii) ~~Selecting of selecting at least one~~ other monoclonal anti-PAMG-1 ~~antibodies antibody~~ ~~exhibiting lower binding specificity than the antibodies of (i) and~~ intended to be used in combination with the ~~pair the antibodies of (i) in one strip test device~~ in order to accurately set up a prescribed threshold of sensitivity to detect a small amount of amniotic fluid in the vaginal secretion of the pregnant woman of the strip test device.

2. (Currently amended) The method of claim 1 wherein highly specific monoclonal antibody of the pair of monoclonal antibodies (i) is localized in a ~~pad-region~~ detector section of ~~the a~~ strip device.

3. (Currently amended) The method of claim 1 wherein one of the highly specific pair of monoclonal antibodies ~~is~~ bound to a marker.

4. (Original) The method of claim 3, wherein the marker is a dye particle.

5. (Currently amended) The method of claim 1 wherein one of the ~~second~~ monoclonal ~~antibody~~ antibodies of the pair (i) is localized in a test region of ~~the a~~ strip device.

6. (Currently amended) The method of claim 5 4, wherein one or more other additional anti-PAMG-1 monoclonal antibodies (ii) are localized in a test region of ~~said a~~ strip device in a predefined proportion to ~~the second- one~~ antibody (i) of the pair.

7. (Currently amended) The method of claim 6 wherein said antibodies (ii) used in combination with said pair of antibodies (i) are used to set up a predefined threshold of sensitivity of said strip device.

8. (Currently amended) The method ~~of claim of any one of claims 1, 6 and 7~~ wherein said anti-PAMG-1 monoclonal antibodies (i) and (ii) being used in combination in predefined proportion are used to set the optimal interval between the value of the background level of said PAMG- 1 in the vaginal secretion, in the range of 0.05 to 0.2 nanogram per milliliter, and the threshold of sensitivity of said strip device, said threshold being in the range 5 to 10 nanogram per milliliter, in order to minimize the likelihood of false negative and false positive results in the detection of small amounts of amniotic fluid in the vaginal secretion of pregnant women.

9. (Withdrawn) A method for detecting leaking amniotic fluid in vaginal secretions, which method comprises detecting binding of a pair of antibodies specific for PAMG-1 in a vaginal secretion.

10. (Withdrawn) The method of claim 9, wherein the pair of antibodies is sensitive to a level of PAMG-1 above background.

11. (Withdrawn) The method according to claim 9, wherein one of the pair of antibodies is immobilized on a solid support.

12. (Withdrawn) The method according to claim 11, wherein the solid support is a membrane through which liquid can travel by capillary action.

13. (Withdrawn) The method according to claim 11, wherein the antibodies are monoclonal antibodies.

14. (Withdrawn) The method according to claim 11, further comprising a second antibody specific for PAMG-1 immobilized on the solid support.

15. (Withdrawn) The method according to claim 14, wherein the ratio of the antibodies immobilized on the solid support provides a threshold level of detection of PAMG-1 of about 5

nanograms per milliliter.

16. (Withdrawn) The method according to claim 13, wherein a monoclonal antibody is selected from the group consisting of M271, produced by hybridoma N271, deposited with the Russian National Collection of Industrial Microorganisms (VKPM) Depository and assigned accession number VKPM-93; M52, produced by hybridoma N52, deposited with the VKPM and assigned accession number VKPM-92; and M42, produced by hybridoma N42, deposited with the VKPM and assigned accession number VKPM-94.

17. (Currently amended) A device comprising a detector section having a mobilizable antibody specific for PAMG-1 which is upstream from a capture section having an immobilized antibody specific for PAMG-1, wherein the capture section also comprises at least one other monoclonal anti-PAMG-1 antibody exhibiting lower binding specificity to PAMG-1 than the mobilizable and immobilizable PAMG-1 antibodies, intended to be used in combination with the mobilizable and immobilizable PAMG-1 antibodies, whereby mobilization of the mobilizable antibody by a fluid sample permits binding of the mobilizable antibody to any PAMG-1 in the sample, and binding of the mobilizable antibody-PAMG-1 complex formed thereby to the immobilized antibody, wherein the mobilizable antibody comprises a marker.

18. (Original) The device of claim 17 wherein the antibodies are monoclonal antibodies.

19. (Original) The device of claim 17, wherein the immobilized antibody is immobilized on a membrane support.

20. (Original) The device of claim 17, wherein the marker is colloidal gold.

21. (Cancelled)

22. (Currently amended) The device of claim 17, wherein the a ratio of the antibodies immobilized on the solid support provides a threshold level of detection of PAMG-1 of about 5 nanograms per milliliter.

23. (Currently amended) The device of claim 17, wherein a ~~the monoclonal~~ mobilizable antibody is ~~selected from the group consisting of~~ M271, produced by hybridoma N271, deposited with the Russian National Collection of Industrial Microorganisms (VKPM) Depository and assigned accession number VKPM-93; ~~and the immobilizable antibody is~~ M52, produced by hybridoma N52, deposited with the VKPM and assigned accession number VKPM-92; ~~and the additional immobilizable antibody is~~ M42, produced by hybridoma N42, deposited with the VKPM and assigned accession number VKPM-94.

24. (New) The device according to claim 17, wherein the ratio of the antibodies immobilized on the solid support provides a threshold level of detection of PAMG-1 when present in a concentration in excess of 3 nanograms per milliliter.

25. (New) A device comprising a detector section having mobilizable antibody specific for PAMG-1, which is upstream from a capture section having an immobilized antibody specific for PAMG-1, wherein the mobilizable antibody is M271, produced by hybridoma N271, deposited with the Russian National Collection of Industrial Microorganisms (VKPM) Depository and assigned accession number VKPM-93, and wherein the immobilizable antibody is M52, produced by hybridoma N52, deposited with the VKPM and assigned accession number VKPM-92, wherein the mobilizable antibody comprises a marker.

26. (New) The device of claim 25, wherein the marker is colloidal gold.